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INSTALLATION AND OPERATION MANUAL

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Please Read This Document before Operating the Machinery

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1. DOCUMENTATION RECORDS

Issue	Documentation Update Details	Date	Approval
1a	Project version 1a developed and issued for internal review	25/10/05	JH
1	First formal issue to customer.	26/10/05	JH
2	Section 3.2 + section 4.12.2 Alarm socket location added	15/11/05	JH

2. INTRODUCTION

2.1 Purpose

This manual provides installation and operation instructions for the Freeze dryer.

This manual and all accompanying documentation must be read before operating the vacuum system.

Important safety information is highlighted as **WARNING** and **CAUTION** instructions; you must obey these instructions. The use of WARNINGS and CAUTIONS are defined below.

2.2 General safety

WARNING: Warnings are given where failure to observe the instruction could result in injury or death to persons.

CAUTION: Cautions are given where failure to observe the instruction could damage to the equipment, associated equipment or process. Refer to the accompanying manufacturers' instruction manuals for the technical data on individual components.

2.3 Unpack and inspect

Remove all packing material.

CAUTION: Remove all packing material before operating system.
If the equipment is damaged notify your supplier and the carrier in writing within three days.

2.4 Installation and Commission

2.4.1 Initial setup

I. Locate the freeze dryer in the required position, ensuring that the floor is adequate to support the equipment and that due consideration is given to:

a) Air flow for ventilation (1metre min)

b) Access to framework panels. (1metre min)

c) Adequate space for maintenance. (1metre min)

CAUTION: The ventilation holes in the framework panels must not be blocked or impeded in any way. If they are, overheating and damage may result.

II. After placement, remove all panels to carry out initial inspection (see sections 3.3 and 3.4). The panels are fitted with lockable latches. To remove panels, unlock the latch using the key provided, press the top end of the latch lever closest to key hole and lift bottom end of lever away from panel.

III. Check the sight glass located on the vacuum pump body (refer to figure 4 and to the manufacturer's literature). The oil level must be between the MAX and MIN level indicators.

IV. The vacuum pump exhaust is internally ducted to a stub pipe located on the rear panel of the condenser unit. Exhaust gases must be ducted away for suitable disposal.

CAUTION: Exhaust gases must be ducted away from the surrounding atmosphere and suitably disposed.

CAUTION: Do not obstruct any vacuum pump exhaust port (refer to manufacturer's manual before operation).

CAUTION: Check that the Gas Ballast control has not been left in the fully closed position (refer to manufacturer's manual before operation).

V. The cooling circuit in the drying unit uses a heat transfer fluid (silicone oil). Check the chamber insulation for signs of oil leaks and confirm that the oil reservoir is approximately half full (see figure 4).

Severn Science Limited engineers to install and commission

2.4.2 Electrical requirements

CAUTION: The unit is factory configured for 415volts (32 amps per phase), three phase supply. Check that your voltage supply is compatible. If you operate the unit on the wrong voltage, you will damage it.

Voltage 415Vac
Frequency 50hz
Loading/power consumption 15 KW
Earthing Class 1 (supply earth required)
Fusing 32A

The freeze dryer is supplied with a 32A socket (3p+N+E). Connect this to a suitable socket.

Ensure that all framework panels are refitted before connecting to any services.

WARNING: Failure to refit all panels prior to connecting to mains power may result in injury or death to the operator.

2.4.3 Mechanical requirements

Compressed air – 6 Bar min, ¼ BSP female
Cooling water - 10°C max, 1/2 BSP female, Flow and Return
Hot water defrost - 40°C min, 1/2 BSP female, Flow and Return
Nitrogen backfill – 1Bar, ⅜ BSP female
Pump exhaust – 25mm plain stub pipe

2.4.4 Lifting and Handling Instructions

2.4.4.1 General

The LSG60 Freeze dryer is designed to be moved as two separate units. The drying chamber assembly (left hand unit) and condenser assembly (right hand unit).
The freeze dryer assembly should therefore be split into these 2 component parts prior to moving. The silicon oil reservoir fitted at the top and left hand side of the drying chamber assembly, must be removed if moving this unit through areas with a height restriction of less than 2110mm.

2.4.4.2 Separation of the LSG60

The LSG60 should be at ambient temperature with the condenser chamber fully drained. The vacuum valve must be fully closed and the shelves in the fully lowered position before commencing separation of the two units.
Ensure that power and all other services are safely and fully disconnected from the LSG60 assembly.
The four jacking feet on each unit should all be in full contact with the ground.

2.4.4.2.1 Draining the Silicon oil fluid circuit

The most efficient means of draining the Silicon oil fluid circuit is by the use of a vacuum pump and catchpot assembly.
The Silicon oil drain valve is located at the rear and bottom of the drying chamber unit. The valve can be identified by its yellow handle.
Connect the vacuum pump and catchpot assembly at this point. By opening the valve the Silicon oil can now be evacuated from the system.

Remove aluminium covers from top of each unit. If required, the Silicon oil reservoir may now be carefully disconnected and removed.

All services that are connected between the condenser unit and the drying chamber unit can now be disconnected:-
1. Unplug all of the (brown) Thermocouple cables from the top rear of the drying chamber unit (see figure 1).
2. Disconnect the three pneumatic lines form the pneumatic control valves. And disconnect / unplug the control valve electrical leads.
3. Disconnect the Nitrogen supplies to the control valves.
4. Unplug the two electrical connections to the Unic 10 valve actuator.
5. Immediately beneath the Unic 10 actuator head is an insulated Ø22mm copper pipe. Remove the short piece of large diameter insulation and disconnect the Straight union found beneath. A second Ø22mm copper pipe under the above item should also be disconnected.
6. Remove the four clamps securing the ISO160 flexible metal pipeline to the Unic 10 valve body.
7. Disconnect the two Harting plugs. One to the side of the drying chamber and a larger one to the rear.
8. Disconnect the Earth link.

9. Disconnect the four grey flexible braided water cooling hoses.
10. Now remove the six 8.0 x 100 socket head capscrews securing the two units together. Two are located in the top horizontal frame member. A further two in the middle horizontal frame member. The remaining pair are in the front and rear verticals, towards the base of the frame work.
11. Un bolt Drying chamber door interlock swith
12. Remove silicon fluid PT100 sensor from rear of chamber (located in pipe junction) and thread back under pipe work.
13. Disconnect nitrogen inlet valve (V13) on chamber side and unplug Drying chamber vacuum sensor.

The two units can now be moved apart.
Take great care when moving these units to avoid damage.
Cap and protect all open pipe work and connections.
Protect the ISO 160 valve from ingress of dirt and foreign bodies.

WARNING: Please note that the drying chamber unit is top heavy. Exercise extreme caution when moving.

2.4.4.3 Moving of the separate LSG60 units

The primary means of moving should be by the use of a suitably rated fork lift truck. For moving through doorways with restricted height and width (1945mm x 810mm minimum) the use of specially designed transport castors are available from Severn Science Ltd. When using these castors, they must be restrained in the frame work by use of the 'quick release pins' supplied. These castors are designed for use on level floors and at a maximum raised height of 8.0 - 10.0mm
(Floor to underside of frame base).

There are 4 Jacking feet positioned towards the corners of each unit. These can be used (if required) for levelling of the units when finally positioned and re-assembled.

2.4.4.4 Re assembling the units

Reassembly of the two units is a reversal of the disconnect procedure. If used, remove all transport castors.
Ensure that the two units are in their final position and that they are at the same height.
All fittings must be clean dry and degreased prior to re-assembly. Application of a smear of suitable pipe sealant (Loctite 577) should be applied to all compression fitting olives before reconnection. Do not over tighten.
The Silicon oil fluid circuit must be vacuum filled to avoid any possibility of trapped air in the system.

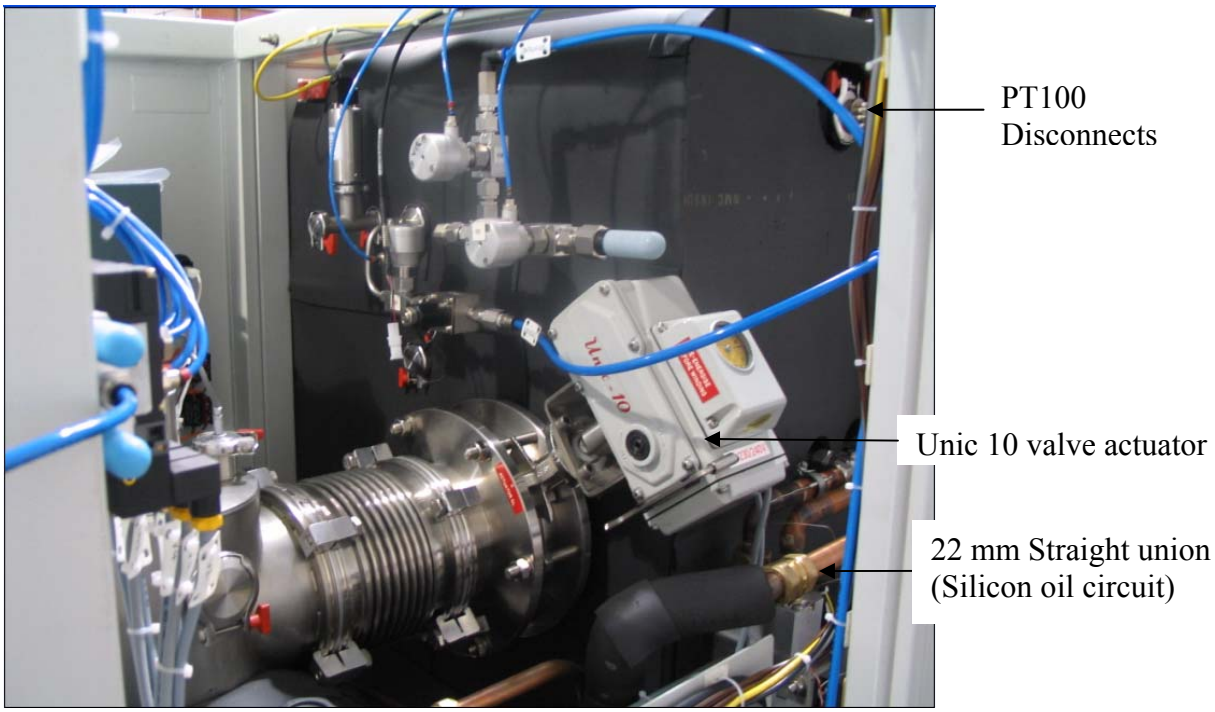

PT100
Disconnects
Unic 10 valve actuator
22 mm Straight union
(Silicon oil circuit)

Figure 1

Figure 2

2.4.5 Additional Documents to be supplied

Electrical circuit diagrams Publication ref 8408
P&ID publication ref 8484
P&ID Key publication ref 1HY085
Alarm schedule Publication ref 1HY086.
Interlock schedule Publication ref 1HY087.
Stoppering Jack choice ref 8516
Declaration of Conformity publication ref 3IW082-F010
Manufacturer's Manuals – non specific

3. OVERVIEW

3.1 General Description

The LSG60 Freeze Dryer is for the purpose of drying a wide range of approximately 150 aqueous products in a variety of different sizes of vials.

Freeze drying is a method used to dehydrate materials via a process involving the sublimation of any water content (in the form of ice) under vacuum conditions. The process can be subdivided into three (3) stages; freezing, primary drying, where the bulk of the water content is removed by sublimation, and secondary drying where residual bound water is removed at higher temperatures. *LYOSCIENCE* freeze dryers are capable of automatically performing all these functions in a controlled and reproducible manner.

The equipment consists of a large vacuum drying chamber mounted alongside a refrigerated condenser with integral vacuum pump. The drying chamber contains nine (9) refrigerated shelves that can be moved up and down via an hydraulically operated ram for stoppering processes. Both condenser and drying chambers are fitted with their own refrigeration systems, with the capability of switching the condenser refrigeration duty to the drying chamber. The temperature of the product shelves can be controlled between +60^{o}C and –60^{o}C.

The condenser unit consist of a cylindrical chamber (290 X 860 mm) with a 160 mm (ISO160) inlet port situated near the front of the chamber and a 40 mm (NW40) outlet port positioned at the rear of the chamber. The chamber condensing coil is cooled directly by an integral CFC free refrigeration system mounted in the base of the unit. During freeze drying, water vapour that is extracted from the product, is condensed onto the coil, resulting in the formation ice. The chamber has a total ice capacity of ~15Kg between defrost cycles. The minimum temperature of the chamber wall under vacuum conditions with no load applied is –80^{o}C.

The condenser inlet is connected to the drying chamber via an electrically actuated high vacuum butterfly valve. The chamber outlet is connected to the inlet of an E2M28 vacuum pump. A transparent Perspex cover at the front of the condenser allows the operator to inspect the ice build up and provides convenient access for cleaning purposes.

The condenser chamber has a hot water defrost utility. An automatic defrost can be incorporated into the Freeze Drying cycle.

An Edwards two stage oil-sealed rotary E2M28 vacuum pump is used to evacuate both condenser and drying chambers. The pump outlet is fitted with a mist filter to prevent oil mist escaping to the atmosphere. The exhaust of the filter is piped to a stub connection at the rear of the freeze dryer, which in turn should be connected to the end user's exhaust extraction system.

Oil collected in the mist filter is continuously returned into the gas ballast port of the pump. The pump is operated on gas ballast to reduce the risk of water condensation in the pump oil (refer also to manufacturers instructions).

The condenser temperature and pressure is monitored with a pirani gauge and a PT100 respectively; data can be continuously displayed on the touch screen if required.

The drying chamber is situated alongside the condenser unit (refer to figure 4). The chamber is fitted with nine temperature controlled product shelves, a refrigeration / heater plant with heat transfer fluid circuit and a shelf stoppering mechanism. A aluminium door at the front of the chamber provides access for loading and unloading and is fitted with two toughened glass view ports (refer to figure 2) which allows the operator to inspect the product during the freeze drying process.

Each shelf contains an internal network of channels through which the heat transfer fluid can flow freely and continuously. Heat is extracted or introduced into the fluid via the refrigeration / heater plant and is then distributed to each shelf in parallel through a common manifold and liquid re circulating pump. Sensors in the fluid circuit provide feedback for closed loop temperature control. Temperature control is achieved by modulating the open/closed state of a valve within the refrigeration system between –100% and 0%. Where –100% is always open, 0% is always closed.
In order to prevent the cooling compressor from free running, when there is no cooling demand for sustained periods of time (cooling valve closed), which could result in oil starvation, a timer control is used. When the Cooling valve has not been called to open by the PID control for 2 minutes, the Auxiliary compressor is turned off. When the Cooling valve is next called to open the compressor restarts.
A PT100 sensor mounted in the fluid circuit provides temperature feedback for the loop.
.

The shelves are mechanically linked to a hydraulically actuated ram with variable pressure settings. The ram moves the shelves up and down allowing automatic stoppering of vials under vacuum and other controlled atmospheres. Operation of the ram is interlocked with a safety switch on the front door ensuring that the actuating mechanism is disabled when the door is opened.

Note: the switch should never be removed or tampered with.

Up to nine (9) product probe sensors (Type T) can be connected and attached to the shelves or the product to enable continuous monitoring of the process.

The operation of the freeze dryer is controlled from the Eurotherm Visual Supervisor (T800) and the Eurotherm 2500 modular process controller.

The Visual Supervisor combines process control, data acquisition, data logging, and setpoint programming and operator functionality. Features include comprehensive event and alarm management and local data logging facilities. The front-end colour touch screen provides the

user interface. Navigation between the User screens is achieved using standard display panes and function keys. User screen descriptions can be found later in this document.

The 2500 modular process controller provides the Input/output interface for the control system, signal conditioning and PID control for the temperature.

These two instruments talk to each other via a serial (RS422) communication link.

The above setup provides a standard control solution for systems such as Freeze dryers.

3.2 Main Interfaces

3.2.1 I/O Interface

The Eurotherm 2500 Process Controller provides the interface for all sensors and plant actuators.
A relay output is provided responding to any alarm activation, and is intended for connection to a Building Management System (BMS).
The connection socket for the alarm relay is located on the service panel on the rear of the freeze dryer.
Refer to page 3 of the Electrical circuit diagrams, Publication ref 8408, for connection details

3.2.2 Operator Interface

The Operator Interface (Visual Supervisor) provides a number of standard (Eurotherm configured) screens and a number of User (Severn Science configured) screens. The user uses a combination of these screens to control and monitor the Freeze Drying Process. This also includes editing and loading Freeze Drying Recipes, monitoring/acknowledging Alarms and security access.

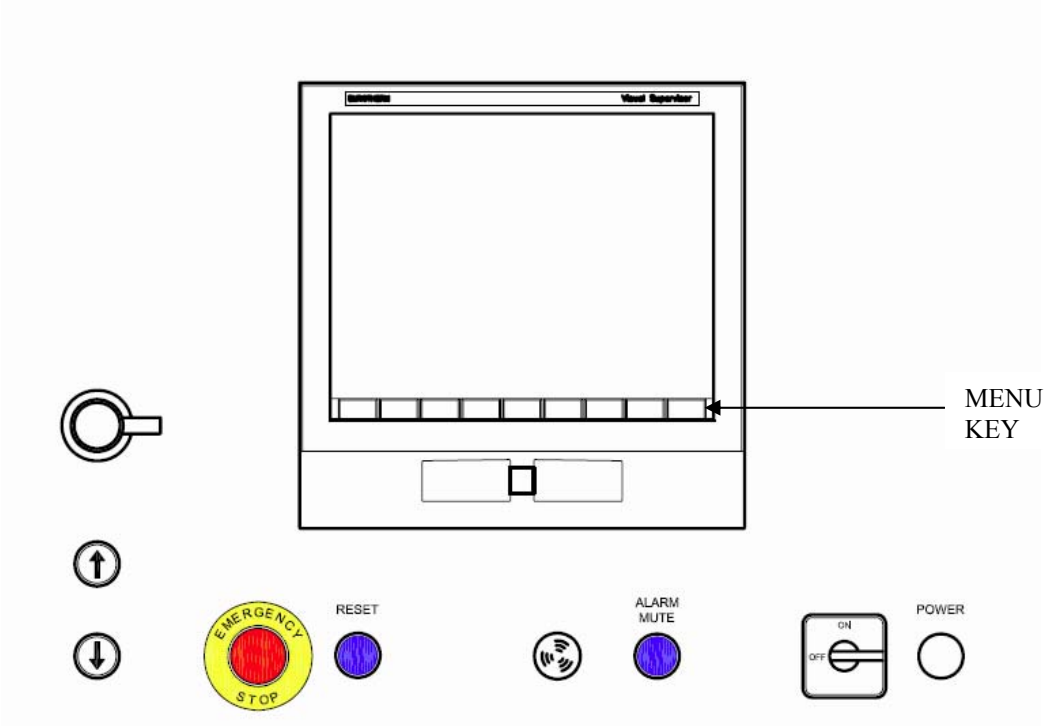


Figure 3

Silicon oil reservior
Drying chamber door
Upper viewport
Lower viewport
Door swing clamps
Condenser Chamber
Drying chamber unit
Condenser unit
Location points for transit castors

Figure 4

4. FUNCTIONS

4.1 Power up

Power up is achieved via the control power switch located below the operator interface (see Figure 3)

A power indicator illuminates to confirm that control system is on. (see Figure 3)

The Visual Supervisor, after a short self-diagnostic routine, starts up automatically in one of two different ways:

Hot start, when control power is returned within 1 hour (factory default) the system uses data about the current program that the Visual Supervisor automatically saves in case of power failure. Using this information, which is preserved through any power loss, the Visual Supervisor is able to automatically restart the program from the point it was.

Cold start, the freeze dryer reverts to its default 'Closed Down' status as follows:

- Compressors off
- Circulation pump off
- Vacuum pump off
- Valves closed
- Freeze-drying cycle not running
- Shelf temperature setpoint set to -20 ^{o}C

Note: The stoppering facility cannot be operated however until the **'RESET'** button is pressed. (See figure 3)

System status display reads 'Closed Down' (see figure 7)

Power down is achieved via the control power switch located below the operator interface (see Figure 3)

The power indicator extinguishes to confirm that control system is off.

System status: Visual supervisor, cooling compressors, fluid pump and vacuum pump off, valves closed. Alarm contact open.

4.2 System Access Control

The Visual Supervisor is set to use individual user accounts. Accounts are configured by the user and allocated to one of the standard access levels as follows:

1. Locked- Default level on power up. Read only with limited navigational ability.

2. Operator- User is able to download recipes run cycles, view alarm history, historical program trending, acknowledge alarms and edit user adjustable parameters.

3. Supervisor- As Operator but in addition can and edit recipes and customise the data logging facility.

4. Administrator- allows individual security accounts to be set up with access rights appropriate to each level of user.

Access- the user is able to log on by the following operation.

1. Access to Access screen = "MENU" key / "ACCESS" button or "ACCESS" pane.
2. Enter Identity.
3. Enter Password.

When user is logged on it is possible to then change their specific password by the following operation.

1. Access to Access screen = "MENU" key / "ACCESS" button / "PASSWDS" button or "ACCESS" pane/ "PASSWDS" button.
2. Enter and confirm new password.
3. Press Change button.

4.3 Operation

4.3.1 Initial start up

Initial start up- before freeze-drying cycles can be run the user first has to switch on the Cooling compressors, Circulation pump, and Vacuum pump.

1. From the Mimic page, press the '**START UP**' button.

The freeze dryer controls to the default parameters (see section **6.2.1.2** below)

System status display reads 'Ready' (see figure 7)

4.3.2 Running automatic cycles

Run automatic cycles- user is able to load recipes, and run/abort freeze-drying cycles.
The *LYOSCIENCE* freeze dryer divides the freeze drying cycle into two separate sequences, the drying profile (program) and the End of Program Sequence (EPS)
Cycle = Program + EPS
Programs can be started as part of a Recipe or independently:

1. *Loading product*

WARNING: The chamber should not be loaded / unloaded when the shelf temperature is less than 0°C. If it is essential to access the chamber under these conditions then protective gloves or suitable PPE should be worn.

CAUTION: The provided 'stoppering jacks' must be placed on all shelves prior to stoppering or damage to the shelves will result

The freeze dryer can be used for both vial and bulk dying. The door to the dying chamber can be opened by first unscrewing the two swing clamps (see figure 4). With the swing clamps rotated clear the door can then be opened using the handle.

Note: Do not use excessive force to open the chamber door. If the drying chamber is under vacuum (for instance when the freeze dryer is first delivered) it will not be possible to open the chamber door.

Note: To open the chamber door if the chamber is under vacuum, first vent the chamber, as follows:

a) From the *Home* screen, press the '**Vent Valve**' icon. The icon changes from Red to Green.

b) When the chamber reaches atmosphere, press the '**Vent Valve'** icon again to close. The icon changes from Green to Red.

2. *Loading/Downloading a recipe*- a recipe is a file that contains values for both the program and the EPS

Parameter variables as follows:

Table 1: Recipe variables

Variable	Description	Limits
PROG NAME	program to run	N/A
NEXT READY	start program automatically	N/A
EPD select	End Point Determination selected	YES or NO
EPD rate mbar/s	End Point Determination fail rate	Max 10 mbar/s Min 0.01 mbar/s
EPD retest [hrs]	End Point Determination duration between tests	Max 60 hrs Min 0.1 hrs
SEC DRY select	Secondary Drying selected	YES or NO
SEC DRY temp [^{o}C]	Secondary Drying temperature	Max 60 ^{o}C Min -40 ^{o}C
SEC DRY time [hrs]	Secondary Drying duration	Max 60 hrs Min 0.1 hrs
BACKFILL select	Automatic Backfill selected	YES or NO
BACKFILL press	Automatic Backfill pressure setpoint	Max 10 mbar Min 0.01 mbar
STOPPER select	Automatic Stoppering selected	YES or NO
FINISH temp [^{o}C]	Cycle completion temperature	Max 60 ^{o}C

		Min -40 ^{o}C

The user is able to load/download a recipe by the following operation

i. Access to the Load/Save page = '**MENU'** key / '**RECIPE'** button
ii. Touch '**File name**'
iii. Select required file from the pick list
iv. Press enter
v. To access the Recipe menu press the '**LOAD**' button

Press the '**DOWNLOAD**' button

The freeze drying cycle will start automatically. The recipe panel changes to blue. The program panel changes to green indicting that the program is now running. The time when the program is due for completion is also displayed together with a number that indicates the number of segments that have been completed.

System status display reads 'Program' (see figure 7)

The freeze dryer will automatically run each segment of the selected program until it is complete. On completion, the cycle will automatically run any End of Program Sequences selected.

During End Point Determination (EPD) the program panel will change to blue and the shelf temperature setpoint will remain unchanged. Program state 'Complete'.

During any of the subsequent sequences the program panel will change to grey. Program state 'Idle'.

3. Running a cycle independently- a program can be initiated directly from the Program menu.

There are three ways to run a program.

a) Run a program now

b) Run a program from a point

c) Schedule a program to run from a time

a) Run a program now

To run a program, first load the required program from the list of stored profiles.

- Press the MENU printed key (see figure 3)
- Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
- Press the PROGRAM button. The *Load/Save Program* screen will be displayed.

- Press the **file name** field . A list of program names will appear in the left half of the screen. From the list, press the name of the program to be loaded.
- Press the green RETURN key. The display returns to the *Load /Save* screen and the **file name** field now displays the name of the program that has been selected.
- Press the LOAD button. At this stage, the selected program can either be run or modified from the *Programmer* screen. The program name, and the program status will also be displayed in the program panel in the top left hand corner of the screen. At this stage, the program status is 'idle'.
- Press the RUN button. The program panel changes to green indicting that the program is now running. The time when the program is due for completion is also displayed together with a number that indicates the number of segments that have been completed (see figure 1).

b) Run a program from a point

Select this function if you wish to run a program from a segment other than the start point of the selected program.

- Press the MENU printed key (see figure 3)
- Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
- Press the PROGRAM button. The *Load/Save Program* screen will be displayed.
- Press the **file name** field . A list of program names will appear in the left half of the screen. From the list, press the name of the program to be loaded.
- Press the green RETURN key. The display returns to the *Load /Save* screen and the **file name** field now displays the name of the program that has been selected.
- Press the LOAD button. At this stage, the selected program can either be run or modified from the *Programmer* screen. The program name, and the program status will also be displayed in the program panel in the top left hand corner of the screen. At this stage, the program status is 'idle'.
- Press the RUN FROM button. A screen headed with the name of the program is loaded. The total running time for the program selected is displayed. Press the **Run From** field (default setting is 00:00:00) and input the time on the numeric keypad (in hours:minutes:seconds) after the start of the program when the program should run from. Press the green RETURN key when inputting is complete. Details of the segment which will be running when the program starts will then be shown in the lower half of the display.

- To run the program, press the RUN key. The *Programmer* screen will appear. The program panel changes to green indicting that the program is now running. The time when the program is due for completion is also displayed together with a number that indicates the number of segments that have been completed (see figure).

c) Schedule a program to run from a time

Security level : Operator or supervisor

Scheduling a program allows the operator to set a time at which a program will start and run automatically.

- Press the MENU printed key (see figure 3)
- Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
- Press the SCHEDULE button. The *Schedule Program* screen will be displayed.
- Press the **File Name** field. A list of program names will appear in the left half of the screen. From the List, press the name of the program to be loaded.
- Press the green RETURN key. The display returns to the *Schedule Program* screen and the **file name** field now displays the name of the program that has been selected.
- Press the **Start Date** field. Input the required start date on the numeric key pad (day:month:year). Press the green RETURN button.
- Press the **Start Time** field. Input the required start time on the numeric key pad (hours:minutes:seconds). Press the green RETURN button.
- To change the number of iterations (number of complete cycle to be performed sequentially), press the **Iterations** field. Input the required number and press the green RETURN button.

Note : The default number of iterations is 1. Entering a value "0" will run the program continuously.

4. Removing product

If the chamber is left under vacuum at the end of the process (as per the program), product can be removed by first ensuring that the isolation valve is closed and then manually venting the chamber.

Note: Do not use excessive force to open the chamber door. If the drying chamber is under vacuum (for instance when the freeze dryer is first delivered) it will not be possible to open the chamber door.

Note: To open the chamber door if the chamber is under vacuum, first vent the chamber, as follows:

c) From the *Home* screen, press the '**Vent Valve**' icon. The icon changes from Red to Green.

d) When the chamber reaches atmosphere, press the '**Vent Valve'** icon again to close. The icon changes from Green to Red.

If the chamber is automatically vented to atmospheric pressure at the end of the process (as per the program), no further action is required before removing the product.

WARNING: The chamber should not be loaded/unloaded when the shelf temperature is less than 0°C. If it is essential to access the chamber under these conditions then protective gloves or suitable PPE should be worn.

5. *Aborting a cycle*- the user is able to abort a running cycle at any stage by the following operation

1. From the Mimic page, press the '**ABORT**' button.

6. *Close down*-the user is able to switch off the compressors and fluid pump by the following operation

1. From the Mimic page, press the '**CLOSE DOWN**' button.

7. *Emergency Stop*- the user is able to isolate power to the Stoppering ram, by activating the E-stop located on the front panel. After an emergency stop condition has occurred, the pressed E-stop button must be released and the '**RESET'** button pressed.

4.4 Creating/Editing the Recipe

1. Access to the Recipe Editor page = '**MENU'** key / '**RECIPE**' button / '**EDIT'** button
2. Touching a value in a recipe column, allows a new value to be entered
3. Press the '**SAVE**' button to save any changes or press the '**SAVE AS**' to make a copy of the file

Control variables as follows:

Table 2: Recipe Parameters

Variable	Description	Limits
PROG NAME	program to run	N/A
NEXT READY	start program automatically	N/A
EPD select	End Point Determination selected	YES or NO
EPD rate mbar/s	End Point Determination fail rate	Max 10 mbar/s

		Min 0.01 mbar/s
EPD retest [hrs]	End Point Determination duration between tests	Max 60 hrs Min 0.1 hrs
SEC DRY select	Secondary Drying selected	YES or NO
SEC DRY temp [^{o}C]	Secondary Drying temperature	Max 60 ^{o}C Min -40 ^{o}C
SEC DRY time [hrs]	Secondary Drying duration	Max 60 hrs Min 0.1 hrs
BACKFILL select	Automatic Backfill selected	YES or NO
BACKFILL press	Automatic Backfill pressure setpoint	Max 10 mbar Min 0.01 mbar
STOPPER select	Automatic Stoppering selected	YES or NO
FINISH temp [^{o}C]	Cycle completion temperature	Max 60 ^{o}C Min -40 ^{o}C

Access level of supervisor or greater is required to make recipe edits.

4.5 Monitoring the Recipe

The Recipe Monitor page can be accessed by touching the MONITOR key from the recipe menu. The following columns are displayed:

RCP The recipe variable
SP The value held in the recipe for each variable
SP(live) The current live value for each variable. Where the SP and SP(live) values differ, the value is highlighted in red, providing a useful diagnostic should a recipe download fail.

4.6 Creating/Editing the Program

4.6.1 Creating a new program

The method used to create new programs is based on editing an existing program and saving the modified program under a new name. When creating a new program for the first time, use the program called "F010" which has been installed into the Controller memory prior to shipping. To load the 'F010' program, follow the instructions below:

a) Press the MENU printed key (see figure 3)

b) Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.

c) Press the PROGRAM button. The *Load/Save Program* screen will be displayed.

d) Press the **file name** field . A list of program names will appear in the left half of the screen. From the List, press the name of the program to be edited.

e) Press the green RETURN key. The display returns to the *Load /Save* screen and the **file name** field now displays the name of the program that has been selected.

f) Press the LOAD button. At this stage, the selected program can either be run or modified. To edit the program, press the EDIT button. Details of the program will appears in the form of a table (referred to as the Editor Screen). Each column of the table represents a segment of the freeze drying process and each row

describes the freeze drying conditions of either temperature or pressure (pressure is controlled by the high vacuum valve which is either open or closed). Individual cells (denoted SP cells) define the temperature or pressure set points for any particular segment. The top row of cells (referred as 'segment headings') define the duration and the function name (e.g., freezing, primary drying etc) of each segment.

To configure the segment headings follow the instructions below:

a) Press the segment heading that must be modified. A box displaying data about the segment will appear. To change the segment name press the **segment** field. Use the keyboard to input the required name. To change the segment duration press the **Duration** field and use the keyboard to input the required time (hours: minutes : seconds).

b) Press the green RETURN key. The *Program Editor* page reappears, showing the new segment name and duration.

Repeat for any segment heading as necessary.

Note : Changing the duration will not be permitted if the "Ramp @ " function has been selected previously anywhere in that segment.

To configure the segment SP cells follow the instructions below:

a) Press the SP cell that must be modified. A box displaying data about the cell will appear. Press the **Type** field. A list of optional functions will be displayed. The choice of functions available include Dwell, Step, Ramp and Ramp@. These function are described in more detail in Table 3).

b) Select the function that is required and press the green RETURN key.

c) Depending on the function selected, time and temperature set point values can then be modified by pressing the appropriate field and entering the value on the numeric keypad (refer to Table 3). Press the DONE button to update the program table (the set point data and code is displayed in each cell) .

Table 3: Function Descriptions and Coding

Function Name	Function Description	SP code	Set point fields
Dwell	Temperature set point is held for duration of segment	D	None
Step	Temperature ramps to temperature set point as fast as possible	S	Temperature
Ramp	Temperature ramps to temperature set point at a constant rate over the duration of the segment	R	Temperature
Ramp@	Temperature ramps to temperature set point at specified ramp rate	R@	Rate (/hr) Temperature

4.6.2 Inserting a segment

To add a new segment to the freeze drying program, follow the procedure below:

a) From the program editor screen, press the heading that will proceed the new segment you wish to insert. A box displaying data about the segment will appear.

b) Press the INS SEG key. The *New Segment* screen will appear.

c) Press the **Segment** field and use the keyboard to type in the segment name.

d) Press the green RETURN button. Press the OK button on the *New Segment* screen. A column will then appear in the program table, representing the new segment.

e) Configure the new segment as per section 4.6.1.

To save the updated program under the same file name after inserting a segment, or to save the program as a new file name, refer to section 4.6.4.

4.6.3 Deleting a segment

To remove a segment from the freeze drying program, following the procedure below:

a) From the program editor screen, press the segment header to be deleted. Details of the segment will appear.

b) Press the DEL SEG button. The *Confirm Delete* screen will appear. Press OK, to confirm delete command.

To save the updated program under the same file name after deleting a segment, or to save the program as a new file name, refer to section 4.6.4.

Note: The first segment of a program can not be deleted.

4.6.4 Save/Save as

To save the updated program under the same file name after editing is complete, or to save the program as a new file name, follow the procedure below. To insert or delete segments prior to saving, see sections 5.2 and 5.3.

a) From the program editor screen, press the MENU button on the printed keypad. From the menu options press the PROGRAMMER button. The *Programmer* screen will appear.

b) Press the PROGRAMS button. The *load /Save Program* screen will appear.

c) To save the edited program under the same file name (shown in the **File Name** field), press the SAVE button.

d) To save the edited program under a new file name, press the SAVE AS button. The *Save As* screen will appear.

e) Press the **File Name** field and enter the new file on the keypad.

f) Press the green RETURN key and the OK buttons to confirm.

4.7 Monitoring the Program

4.8 Trends

Security level: Operator or Supervisor

To view a summary of the program status in graphical form, follow the procedure below:

a) Press the program panel in the top left hand corner of the screen. The *programmer* screen will appear.

b) Press the PRE-PLOT button. A graph will appear on the screen, headed with the title of the program in use. Process parameters are logged on the 'Y' axis as a function of time ('X' axis) with the direction of time, past to future, moving from left to right. A curve showing the pre - programmed target values, spanning 4 minutes before and after real time, is plotted in pink. A separate curve, plotted in red, gives the actual recorded value for the 4 minutes leading up to the current time. Current time is represented by a vertical line in the middle of the graph.

4.9 Setup

Security level: Supervisor

The Setup page can be accessed by touching the SETUP key from the Home page.
The following sub sequences can be setup:

4.9.1 End Point Determination

End Point Determination (EPD) is an automatic pressure rise test that can be run directly after the main drying phase, used to determine if the product has reached the required level of dryness. If this level (determined by the rate of pressure rise in the chamber with the vapour valve closed) has not been reached then drying continues with temperature and pressure settings as per the last segment of the program.

Select/unselect the automatic backfill option by pressing the appropriate field which will toggle between YES and NO.
Note: this can also be used to abort this sequence at any stage.

The rate and repeat test time set point values can be modified by pressing the appropriate field and entering the value on the numeric keypad.

Note: these changes will be effective immediately, overwriting any previously downloaded recipe values.

4.9.2 Secondary Drying

Secondary Drying is used to continue drying for a period (user adjustable) at a set temperature (user adjustable) after the main program and End Point Determination (if used) have finished.

Select/unselect the automatic backfill option by pressing the appropriate field which will toggle between YES and NO.
Note: this can also be used to abort this sequence at any stage.

The time and temperature set point values can be modified by pressing the appropriate field and entering the value on the numeric keypad.

Note: these changes will be effective immediately, overwriting any previously downloaded recipe values.

4.9.3 Automatic Backfill

Automatic Backfill is used to bring the Product chamber up to a desired level of pressure (user adjustable), by introducing nitrogen, prior to stoppering. Alternatively the pressure setpoint can be set to atmosphere to fully vent the chamber with nitrogen.

Select/unselect the automatic backfill option by pressing the appropriate field which will toggle between YES and NO.
Note: this can also be used to abort this sequence at any stage.

The pressure set point value can be modified by pressing the appropriate field and entering the value on the numeric keypad.

Note: these changes will be effective immediately, overwriting any previously downloaded recipe values.

4.9.4 Automatic Stoppering

CAUTION: The provided 'stoppering jacks' must be placed on all shelves prior to stoppering or damage to the shelves will result

Note: The stoppering facility cannot be operated however until the **'RESET'** button is pressed. (see figure 3)

Automatic stoppering, when used with stoppering jacks (see figure 5), is used to fully stopper semi stoppered vials by hydraulically closing the product shelves. Pressure switches are used for feedback to the control system to indicate the fully stoppered and fully home positions (see figure 6). These switches can be adjusted to increase/reduce stoppering pressure. This activity should only be undertaken with Severn Science assistance.

Select/unselect the automatic backfill option by pressing the appropriate field which will toggle between YES and NO.
Note: this can also be used to abort this sequence at any stage prior to it starting.

Note: these changes will be effective immediately, overwriting any previously downloaded recipe values.

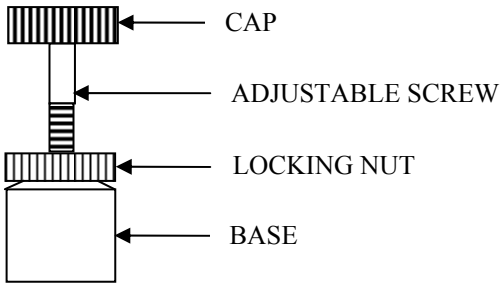


Figure 5

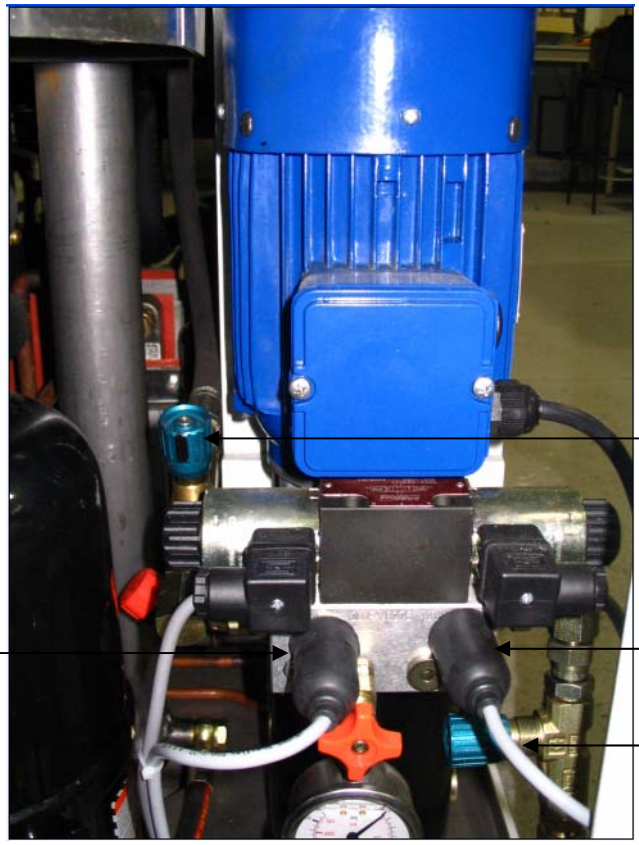


Figure 6

4.10 Manual Operation

Security level: Supervisor

Manual mode- user is able to control the system, by individually operating components from the mimic screen. Manual mode is accessible by pressing the Manual button (Supervisor level) on the Home screen. Controllable parameters are as follows:

1. Condenser compressors
2. Cool Cond valve
3. Cool Liq valve
4. Vacuum pump
5. Diathermic pump
6. Vacuum valve
7. Vapour valve
8. Condenser chamber air inlet valve
9. Condenser chamber defrost valve
10. Condenser chamber drain valve
11. Product chamber air inlet valve
12. Product chamber N^2 backfill valve
13. Product chamber N^2 isolation valve

14. Shelf temperature Auto/Man control
15. Shelf temperature control output

4.11 Interlocks

4.11.1 Hardwired Interlocks

For a complete list of interlocks refer to "Interlock schedule" Publication ref 1HY087.

4.11.2 Software Interlocks

For a complete list of interlocks refer to "Interlock schedule" Publication ref 1HY087.

4.12 Alarms

4.12.1 Alarm Types

Alarm severities are listed in "Alarm schedule" Publication ref 1HY086.

All active alarms are displayed locally and the T800 Run relay is de-energised.

4.12.2 Alarm Display and Acknowledgement

The Alarm pane displays information relating to current alarms.
When at least one Alarm is active but unacknowledged the Alarm pane flashes red, when the alarm is active but acknowledged the Alarm pane is steady red and if alarm has cleared but is unacknowledged the Alarm pane flashes black.
Only the most recent alarm tag is displayed, on the Alarm pane, if multiple active alarms exist.

Acknowledgement- user is able to acknowledge alarms individually or all together using the following operation:

1. Access to Alarm pane = "MENU" key / "PROGRAMMER" button / "ALARM" button or "PROGRAMMER" pane / "ALARM" pane.
2. Press Acknowledge or Acknowledge all button.

History- an alarm history screen displays a list of current and previously active alarms indicating when they occurred and if appropriate when they were cleared or acknowledged. A total of 250 alarms can be displayed and when this is exceeded the oldest alarm is deleted when a new alarm occurs.

User interfacing- any active unacknowledged alarm de-energises the T800 Run relay output.
A relay output is provided responding to any alarm activation, and is intended for connection to a Building Management System (BMS).
The connection socket for the alarm relay is located on the service panel on the rear of the freeze dryer.
Refer to page 3 of the Electrical circuit diagrams, Publication ref 8408, for connection details

4.13 Historical Logging

Data can be logged to the 16MB internal memory during the freeze drying cycle. Data is recorded as a text file (.ASC) and can be later imported into most spreadsheet applications. The Archive interval is user adjustable (max rate 5secs). Log files can be given an 8-character file name (using MS-DOS constraints).

The data logged to disk is:

1. Active alarms
2. Shelf Temp PV
3. Shelf Temp SP
4. Shelf Press PV
5. Shelf Press SP
6. Condenser Temp PV
7. Condenser Press PV
8. Vacuum Valve position
9. Vapour Valve position
10. Liq_Cool status
11. Defrost status
12. Drain status
13. Event history
14. Time/Date

Naming a Log file- the user is able to name a Log file using the following operation.

1. Access to Logging Groups screen = "MENU" key / "LOGGING" button / "GROUPS" button or "LOGGING" pane / "GROUPS" button.
2. Enter File Name.

Setting the Archive interval- the user is able to set the Archive interval using the following operation.

1. Access to Logging Groups screen = "MENU" key / "LOGGING" button / "GROUPS" button or "LOGGING" pane / "GROUPS" button.
2. Enter Archive Interval (hh.mm.ss)

The user is able to start logging manually using the following operation:

1. Access to Logging screen = "MENU" key / "LOGGING" button / "MONITOR" button or "LOGGING" pane / "MONITOR" pane.
2. Select logging ON.
3. To stop logging select OFF.

The logged data from the internal memory storage can be archived by the user to a removable device such as a floppy disk or memory stick. The data can be restored for viewing in either a text editor or a spreadsheet.

The user is able to archive log files using the following operation:

1. Access to Archive Manage page = "MENU" key / "LOGGING" button / "MANAGE" button or "LOGGING" pane / "MANAGE" pane.
2. Press '**EXPORT'** or '**EXPORT ALL'** button

'Export' causes the currently displayed file to be copied to the floppy disk or USB device, as selected.
'Export All' causes all files in the internal archive to be copied to the floppy disk or USB device. If the device becomes full during archive a message appears asking the user to fit a new disk.

5. OPERATOR DISPLAYS

5.1 System Mimics

5.1.1 Home

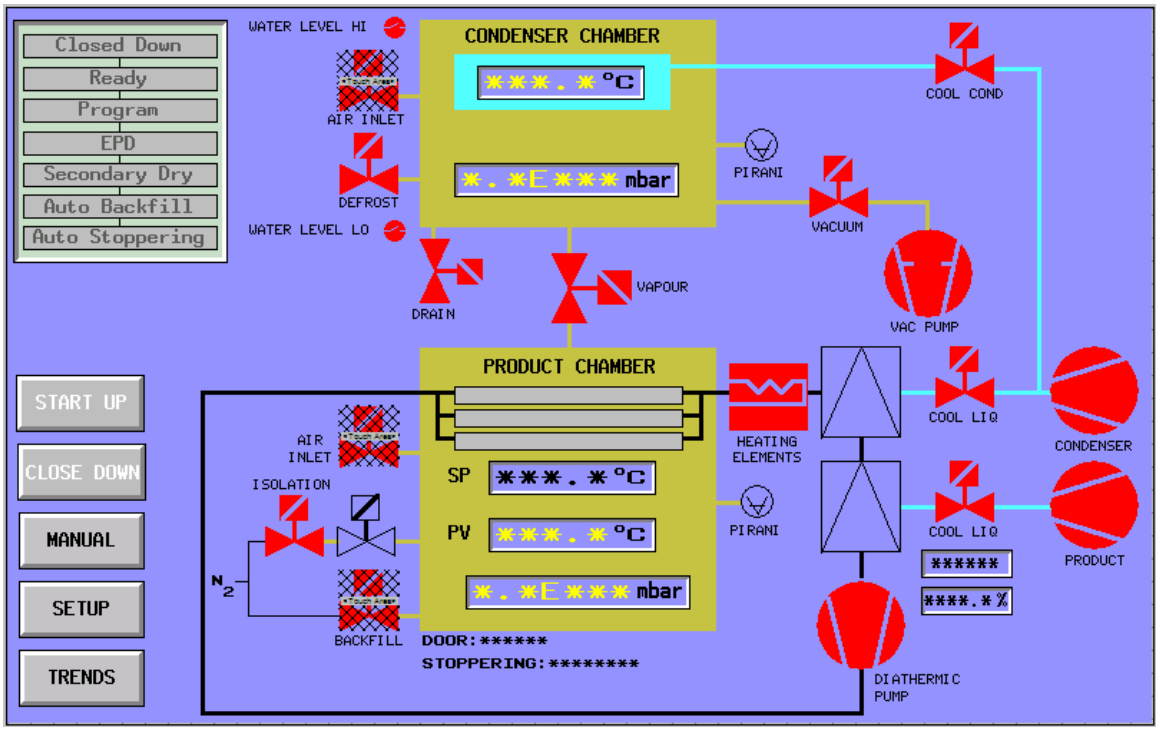


Figure 7

5.1.2 Setup

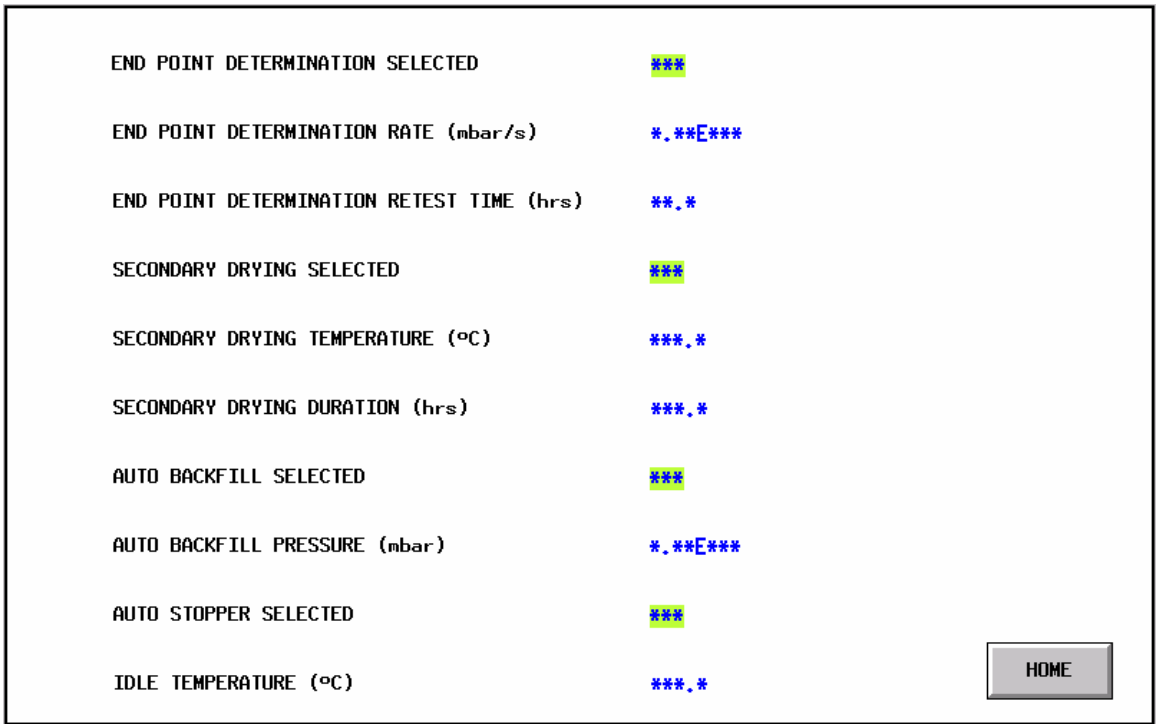

END POINT DETERMINATION SELECTED ***
END POINT DETERMINATION RATE (mbar/s) *.**E***
END POINT DETERMINATION RETEST TIME (hrs) **.*
SECONDARY DRYING SELECTED ***
SECONDARY DRYING TEMPERATURE (ºC) ***.*
SECONDARY DRYING DURATION (hrs) ***.*
AUTO BACKFILL SELECTED ***
AUTO BACKFILL PRESSURE (mbar) *.**E***
AUTO STOPPER SELECTED ***
IDLE TEMPERATURE (ºC) ***.*
HOME

Figure 8

5.1.3 Trend

Example of a single trend page

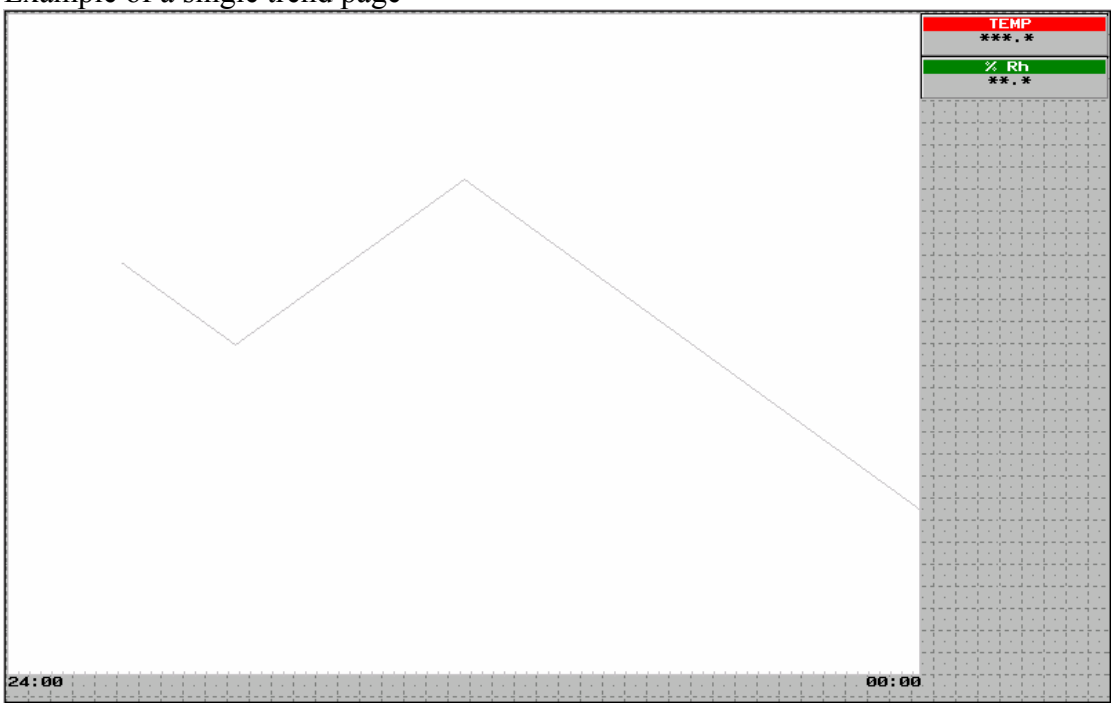
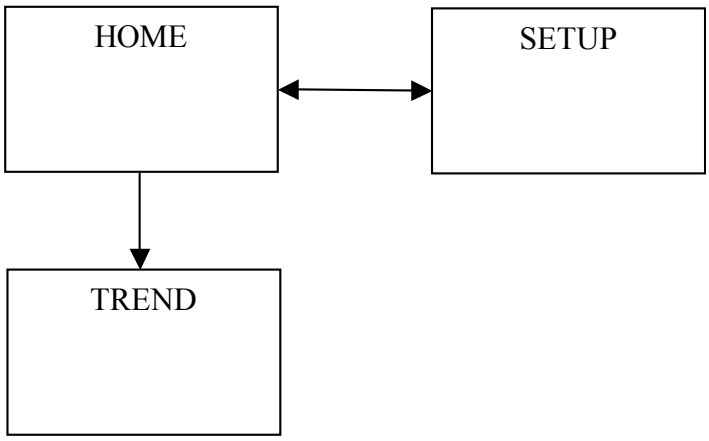


Figure 9

5.2 Display Navigation

Navigation between displays is as follows:



6. MAINTENANCE

WARNING: There is no safety interlock fitted to the electrical cabinet door. Ensure that the electrical supply is isolated before starting any maintenance work.

6.1 Planned Maintenance

When performing the following operations, refer to the components own working instructions for details on how to carry out the specified items; all of the necessary working instructions are supplied with this manual.

6.1.1 Daily Maintenance

- Check oil level in vacuum pump
- Check chamber door o-ring

6.1.2 Weekly Maintenance

- Check oil level in vacuum pump
- Check silicon oil level

6.1.3 Six monthly

- Check operation of refrigeration cooling fans
- Check silicon fluid circuit for leaks
- Change the vacuum pump oil
- Calibrate gauges

6.1.4 Calibration

It is recommended that all gauging and sensors fitted to this unit be returned to SSL (or a relevant competent body) for service and calibration at least every 12 months. The time interval between services must to be reviewed by the customer during the units operating life.

6.2 Recommended Spares

6.2.1 General

Table 4: Recommended Spare Parts List

Description	Part No	Manufacturer
AXIAL VALVE SERVICE KITS	4243 00 10 30 X 1 (3/8") 4243 00 15 30 X 1 (1/2")	LEGRIS
CHAMBER DOOR SEAL.	Ø10.0 silicon 'O' ring chord x 4 metres.	SEVERN SCIENCE
CONDENSER ACRYLIC VIEWPORT SEAL.	Ø305 i/d x 5.0 sect silicon 'O' ring.	SEVERN SCIENCE
SILICON OIL CIRCULATION PUMP	HB527.0003 Huber Unipump ll, 2 stage.	HUBER
SILICON OIL.	LS-1-013 (5ltr)	SEVERN SCIENCE
VACUUM PUMP OIL	H110 25 015. (1ltr)	SEVERN SCIENCE
HYDRAULIC OIL	Mineral oil SAE 30/10 30C/S (2.5ltr required)	SEVERN SCIENCE
PNEUMATIC PILOT VALVES.	5/2 sol/spring 520 00 380 24vdc Pressure switch 349 00 18	ASCO
NW40 VACUUM ISO VALVE SERVICE KIT.	VAT. Part No. 241079	VAT
PNEUMATIC NUPRO VALVE.	8.0MM and 12.0mm Bellows kit SS-4BA-K1 Stem kit SS-8BK-K5 Body seal kit SS-4BGO-K5-T	SWAGELOK
HYDRAULIC POWER PACK	Hydraproducts Limited. Tel. 01452 544052.	Hydraproducts Limited
AI2-TC	2 ch. Isolated universal analog IP with CJC	Eurotherm
AI2-DC	2 ch. Isolated universal analog IP for PT100 and volts	Eurotherm
AI4-TC	4 ch. Non isolated T/C, with CJC	Eurotherm
AO2	2 ch. Isolated analogue output mA, volts	Eurotherm
DI8C	8 ch. Non isolated digital IP (contacts only)	Eurotherm
DO4	4 ch. Digital output logic output 10mA max	Eurotherm
RLY4-FUSE	4 ch. Relay output module with disconnects	Eurotherm
	WATLOW FIREROD CARTRIDGE HEATER, 1/2" DIA x 8 1/4" LONG,	Watlow

	240V 400W, 1/4" COLD AT DISC END, 1/2" COLD AT LEAD END, 39" TEFLON LEAD AND SEAL.	
SVDA-3V25-AO2	SOLID STATE RELAY 25A	Eurotherm

6.3 Edwards vacuum pump

For the Edwards Vacuum pump refer to the individual manufacturers literature for spares.

6.4 Manufacturers literature

Manufacturers literature for all major components have been included.

6.5 Self Diagnostic Facilities

Both T800 and 2500 perform their own self check routines on start-up.
2500 I/O module or hardware errors and Modbus communication failures are checked for within the configurations and raise alarms if a fault is detected.

7. TECHNICAL SPECIFICATIONS

Table 5: Technical Specifications

FUNCTION	MODEL	PERFORMANCE
Minimum condenser temperature (@ 25°C ambient)	**LSG60**	-80°C
Minimum shelf temperature (@ 25°C ambient)	**LS40** **LS60**	-40°C -60°C
Shelf cool down times (with both refrigeration units and with no load, from 23 °C)	**LSG60** (to -35°C) (to –40°C) (to –55°C) (to –60°C)	 20 minutes 22 minutes 31 minutes 35 minutes
Maximum shelf temperature	**LSG60**	60°C
Temperature uniformity (between shelves measured at the inlet)	**LSG60** (to 0°C) (to –20°C) (to –40°C) (to –60°C)	 ± 0.6°C ± 0.8°C ± 1.5°C ± 2.0°C
Temperature uniformity (across each shelf measured along the front)	**LSG60** (to 0°C) (to –20°C) (to –40°C) (to –60°C)	 ± 0.5°C ± 0.8°C ± 1.1°C ± 1.9°C
Temperature control	**LSG60**	± 0.2°C
Condenser capacity	**LSG60**	15 kg
Defrost time (water inlet temp @ 40°C)	**LSG60**	Approx 10 minutes
Vacuum Pump 1. Type 2. Nominal Pumping speed 3. Pump down time (to 0.5 mbar)	**LSG60**	 Edwards E2M28 28 m^3/hr Approx 10 minutes
Electrical a) Supply b) Power rating	**LSG60**	 415V, 50Hz, 3 ph, 15 KW
Dimensions (w x h x d) (not including oil reservoir)	**LSG60**	1400 x 1940 x 1000 mm
Weight	**LSG60**	XXX Kg
Shelf area	**LSG60**	157 m^2
Noise	**LSG60**	XXX dB

8. ENVIRONMENT SPECIFICATIONS

- Temperature Operation 0 to + 30°C
- Temperature Storage -10 to +70°C
- Humidity Operation 50 to 85% RH (non condensing)
- Humidity Storage 5 to 95% RH (non-condensing)
- Protection IP22 (Electrical panel and front panel IP54)

9. GLOSSARY

PID	Proportional / Integral / Derivative
2500	Eurotherm 2500 Input / Output unit
FLASH memory	A memory chip that can be rewritten and hold its content without power
RTD	Resistance Temperature Detector
T800	Eurotherm T800 Visual Supervisor unit
BMS	Building Management system
RS232	Serial communications port
PPE	Personal Protective Equipment
EPS	End of Program Sequence
EPD	End Point Determination